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| 10/625,869 | 07/23/2003 | Nicholas Lawrence Abbott | 032026-0736 | 8011 |

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| EXAMINER |
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TRAN, MY CHAU T

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| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/625,869 | Applicant(s) ABBOTT ET AL. | |
| | Examiner MY-CHAU T. TRAN | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicants' amendment and response filed 02/07/2006 are acknowledged and entered.
2. Claims 1-20 were pending. Applicants have amended claims 1, 8, and 16. No claims were cancelled and/or added. Therefore, claims 1-20 are currently pending.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed on 03/14/2006 has been reviewed, and its references have been considered as noted on PTO-1449 form.

Withdrawn Objection(s) and /or Rejection(s)

4. The objection of the disclosure for the informality of not including the current status of all nonprovisional parent applications referenced has been withdrawn in light of applicant's amendments of the instant specification.
5. The rejections of claims 8 and 16 under 35 USC 112, second paragraph, as being indefinite regarding the phrase '*a portion of*' has been withdrawn in light of applicant's amendments of claims 8 and 16, wherein the amendment added the limitation of "*capable of recognizing and binding epitopes and binding domains associated with microscopic pathogens*".

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6. The rejections of claims 1-3, 6, 10, 14, 16, and 17-20 under 35 USC 102(b) as being anticipated by Gupta et al. (*Science*, **1998**, 279(5359), pgs. 2077-2080) has been withdrawn in light of applicant's amendment of claim 1, wherein the amendment added the limitation of "*wherein the biochemical blocking layer comprises biochemicals*".

7. The rejection of claims 1, 2, 4, 14, 15, and 16 under 35 USC 102(e) as being anticipated by Abbott et al. (US 6,277,489 B1) has been withdrawn in light of applicant's amendment of claim 1, wherein the amendment added the limitation of "*wherein the biochemical blocking layer comprises biochemicals*".

8. The rejection of claims 1-3, 6, 7, 10, 14, and 16-20 under 35 USC 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1) has been withdrawn in light of applicant's amendment of claim 1, wherein the amendment added the limitation of "*wherein the biochemical blocking layer comprises biochemicals*".

9. The rejection of claims 1-7, 10, 14, and 16-20 under 35 USC 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1; *filing date of 07/31/1998*) and Weetall (*Applied Biochemistry and Biotechnology*, **1993**, 41, pgs. 157-188) has been withdrawn in view of applicant's amendment of claim 1, wherein the amendment added the limitation of "*wherein the biochemical blocking layer comprises biochemicals*".

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10. The rejection under the judicially created doctrine of obviousness-type double patenting of claims 1, 14, and 16 over claims 1-3, 21, and 23 of U.S. Patent No. 6,277,489 B1 has been withdrawn in view of applicant's amendment of claim 1, wherein the amendment added the limitation of "*wherein the biochemical blocking layer comprises biochemicals*".

Maintained Rejection(s)

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 1, 8, 9, 11, 12, 16, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-10, and 14 of copending Application No. 10/934,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of has overlapping scope since the device of copending Application No. 10/934,023 the instant application is generic to the device of the presently claimed device of copending Application No. 10/934,023, or in other words, claims 1, 8, 9, 11, 12, 16, and 20 are anticipated by claims 1, 8-10, and 14 of copending Application No. 10/934,023. Specifically, the structural features of both devices are a multilayered support comprising a biochemical blocking layer, a binding agent, and a liquid crystal compound. Thus, the examined claims would have been obvious over the claims of copending Application No. 10/934,023.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments directed to the above provisionally rejected under the judicially created doctrine of obviousness-type double patenting were fully considered but were not deemed persuasive for the following reasons.

[1] Applicant alleges that the copending Application No. 10/934,023 is not obvious over the apparatus of the examined claims because the copending Application No. 10/934,023 does not teach or suggest '*the surface of the biochemical blocking layer being a rubbed surface*'. Thus, the copending Application No. 10/934,023 is not obvious over the apparatus of the examined claims.

This is not found persuasive for the following reasons:

[1] It is the examiner position that the copending Application No. 10/934,023 is obvious over the apparatus of the examined claims because do the copending Application No. 10/934,023 does teach or suggest the instant claimed structural features of "*biochemical blocking layer*". The instant claimed structural features of "*biochemical blocking layer*" comprise '*a biochemical blocking compound chemically immobilized on a support*' and '*biochemicals*'. Claim 1 of copending Application No. 10/934,023 discloses a blocking layer on the surface of the substrate and in contact with the liquid crystal. In addition, claim 8 of copending Application No. 10/934,023 claimed that the blocking layer is bovine serum albumin, i.e. a biochemical. Accordingly, the copending Application No. 10/934,023 do teach or suggest the instant claimed structural features of "*biochemical blocking layer*". The limitation of "*the surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface*" is interpreted as

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a process limitation and the manner/mode of operation of the instant claimed apparatus does not differentiate from the prior art apparatus when the prior art apparatus meets all the limitation of the instant claimed apparatus. See MPEP § 2114. Moreover, the structural feature impart by this limitation is that the “*biochemical blocking layer*” is in contact with the “*liquid crystals*”. This structural feature is claimed in claim 1 of copending Application No. 10/934,023. Therefore, the copending Application No. 10/934,023 is obvious over the apparatus of the examined claims, and the rejection is maintained.

New Rejection(s) – Necessitated by Amendment

14. *The instant invention recites a substrate structure for use in a liquid crystal assay device, i.e. an apparatus. The term ‘rubbed’ is use to define the substrate and this term is interpreted as the functional/property limitation of the instant claimed substrate for it does not impart any structural feature for this instant claimed substrate.*

The structural feature of the apparatus (substrate) comprises (a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer.

The biochemical blocking layer comprises biochemicals.

The biomolecule recognition agent comprises a recognition site.

The recognition site is capable of selectively recognizing a target species. This limitation is interpreted as the functional/property limitation of the instant claimed recognition site.

The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface.

The biochemical blocking layer resists non-specific adsorption of non- target species. This limitation is interpreted as the functional/property limitation of the biochemical blocking layer.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-3, 6-14, and 16-20 are rejected under 35 U.S.C. 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1; *filing date of 07/31/1998*) and Anawis et al. (US Patent 5,091,318).

The applied reference has a common inventor, Nicholas L. Abbott, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that

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the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Abbott et al. disclose a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see e.g. col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass (refers to instant claim 14) (see e.g. col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; fig 2). Additionally, the surface of the substrate is derivatized with reactive functional group wherein the organic layer is attached (refers to instant claimed biochemical blocking layer)(see e.g. col. 21, lines 8-16; col. 21, lines 33-67). The organic layer (refers to the instant claimed a biochemical compound) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, i.e. binding characteristics, is altered by attaching a monovalent moiety (see e.g. col. 25, lines 41-56). The recognition moiety (refers to instant claimed biomolecule recognition agent and claim 16) includes organic groups or biomolecules such as protein, nucleic acid, or peptide (see e.g. col. 26, lines 17-48). Additionally, the recognition moiety is attached to the organic layer through a spacer arm (refers to instant claims 2 and 7)(see e.g. col. 20, lines 4-52; col. 24, lines 60-66). The mesogenic layer is compound or mixture of compounds that is liquid crystals (see e.g. col. 10, lines 26-28; col. 30, lines 30-47). In one type of device, the device (refers to instant

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claim 20) comprises a first substrate with a first organic layer that comprises a recognition moiety, which interact with the analyte, a second substrate, and a mesogenic layer between the first and second substrate (see e.g. col. 5, lines 44-59; col. 20, lines 4-52; col. 40, line 36 thru col. 41, line 66). In another type of device, the optical cell (refers to instant claims 17 and 19) comprises two supports, an anisotropic gold films, two self-assembled monolayers, a spacer that separate the two self-assembled monolayers, and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claim 18)(see e.g. col. 40, lines 36 thru col. 41, line 41; fig. 2). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. col. 42, lines 34-38). The two self-assembled monolayers comprises a self-assembled monolayer form from biotin-(CH₂)₂[(CH₂)₂O]₂NHCO(CH₂)₁₁SH(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent) and a self-assembled monolayer form from CH₃(CH₂)₇SH(C₈SH) (refers to instant claimed second surface)(see e.g. col. 40, line 56 thru col. 41, line 19). The support is a glass slide (see e.g. fig. 2).

Additionally, the claimed invention further differs from the prior art teachings only by the recitation of the following process limitations: a) "*The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface*"; b) for claim 3, "*the biomolecule recognition agent is deposited on the same side of the support as the biochemical blocking layer before the biochemical blocking layer is rubbed*"; and for claim 10 "*at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the*

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at least two regions of the rubbed surface have different sensitivities towards the target species".

These limitations do not differentiate the claimed apparatus from the apparatus of Abbott et al.

since the apparatus of Abbott et al. meets all the structural limitation of the claimed apparatus.

See MPEP § 2114, which states:

***MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM
FROM THE PRIOR ART***

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (The preamble of claim 1 recited that the apparatus was "for mixing flowing developer material" and the body of the claim recited "means for mixing ..., said mixing means being stationary and completely submerged in the developer material". The claim was rejected over a reference which taught all the structural limitations of the claim for the intended use of mixing flowing developer. However, the mixer was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.).

Here, the apparatus of Abbott et al. comprises a support, an organic layer attached to the support (refers to instant claimed biochemical blocking layer), and a recognition moiety attached to the organic layer (refers to instant claimed biomolecule recognition agent), and thus meets all the structural limitation of the claimed apparatus.

The device of Abbott et al. differs from the presently claimed invention by failing to disclose that the biochemical blocking layer comprises biochemical such as blocking agent of bovine or equine serum albumin.

Anawis et al. disclose a device for detecting the presence of an analyte (antibody) in a test sample. The assay device includes a solid phase and the ligand (antigen) is immobilized upon the solid phase (see e.g. col. 2, lines 52-55). In order to prevent non-specific binding of protein to the solid phase when the reaction mixture containing a specific binding member is contacted to the solid phase by using a blocking agent such as bovine or equine serum albumin.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose that the biochemical blocking layer comprises biochemical such as blocking agent of bovine or equine serum albumin as taught by Anawis et al. in the device of Abbott et al. One of ordinary skill in the art would have been motivated to disclose that the biochemical blocking layer comprises biochemical such as blocking agent of bovine or equine serum albumin in the device of Abbott et al. for the advantage of prevent non-specific binding of the analyte such as protein since both Abbott et al. and Anawis et al. disclose an assay device for detecting binding of an analyte on the surface of a solid phase (Abbott: col. 40, lines 36-38; Anawis: col. 7, lines 15-19). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Abbott et al. and Anawis et al. because both disclose Abbott et al. and Anawis et al. immobilizing bovine serum albumin on the surface of the support (Abbott: col. 42, lines 2-20; Anawis: col. 2, lines 52-55).

Therefore, the combine teachings of Abbott et al. and Anawis et al. do render the apparatus of the instant claims *prima facie* obvious.

Response to Arguments

18. Applicant's arguments directed to the above 35 USC 103(a) rejection were fully considered but were not deemed persuasive for the following reasons.

[1] Applicant contends that the combine teachings of Abbott et al. and Anawis et al. is not obvious over the apparatus of the instant claims because neither Abbott et al. nor Anawis et al. disclose 'a biochemical blocking layer that is rubbed, as recited in claim 1 of the present invention'. Thus, the combine teachings of Abbott et al. and Anawis et al. is not obvious over the apparatus of the instant claims.

This is not found persuasive for the following reasons:

[1] It is the examiner position that the combine teachings of Abbott et al. and Anawis et al. is obvious over the apparatus of the instant claims because the combine teachings of Abbott et al. and Anawis et al. do teach or suggest the instant claimed structural features of “*biochemical blocking layer*”. The instant claimed structural features of “*biochemical blocking layer*” comprise ‘*a biochemical blocking compound chemically immobilized on a support*’ and ‘*biochemicals*’. Abbott et al. disclose an organic layer attached to a support, but the organic layer does not include biochemicals. Anawis et al teach this deficiency. Accordingly as fully discussed in the above rejection, the combine teachings of Abbott et al. and Anawis et al. teach or suggest the instant claimed structural features of “*biochemical blocking layer*”. The limitation of “*the surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface*” is interpreted as a process limitation and the manner/mode of operation of the instant claimed apparatus does not differentiate from the prior art apparatus when the prior art apparatus meets all the limitation of the instant claimed apparatus. See MPEP § 2114. In addition, Abbott et al. disclose that liquid crystals are ‘*extraordinary sensitive to external perturbations*’ (see col. 1, lines 36-65) such that whether the surface of the substrate is rubbed before or after the ‘anchoring’ of the liquid crystal would result in the same effect, i.e. “*drive a uniform anchoring of liquid crystals*”. Moreover, the structural feature impart by this limitation is that the “*biochemical blocking layer*” is in contact with the “*liquid crystals*”. This structural feature is taught by Abbott et al. wherein the organic layer anchor the mesogenic layer, i.e. the liquid

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crystal (see col. 17, lines 62-64). Therefore, the combine teachings of Abbott et al. and Anawis et al. is obvious over the apparatus of the instant claims, and the rejection is maintained.

19. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US Patent 6,284,197 B1; *filing date of 07/31/1998*) and Anawis et al. (US Patent 5,091,318) as applied to claims 1-3, 6-14, and 16-20, and further in view of Weetall (*Applied Biochemistry and Biotechnology*, 1993, 41, pgs. 157-188).

Abbott et al. disclose a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see e.g. col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass (refers to instant claim 14) (see e.g. col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; fig 2). Additionally, the surface of the substrate is derivatized with reactive functional group wherein the organic layer is attached (refers to instant claimed biochemical blocking layer)(see e.g. col. 21, lines 8-16; col. 21, lines 33-67). The organic layer (refers to the instant claimed a biochemical compound) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, i.e. binding characteristics, is altered by attaching a monovalent moiety (see e.g. col. 25, lines 41-56). The recognition moiety (refers to instant claimed biomolecule recognition agent and claim 16) includes organic groups or biomolecules such as protein, nucleic acid, or peptide (see e.g. col. 26, lines 17-48). Additionally, the recognition moiety is attached to the organic layer

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through a spacer arm (refers to instant claims 2 and 7)(see e.g. col. 20, lines 4-52; col. 24, lines 60-66). The mesogenic layer is compound or mixture of compounds that is liquid crystals (see e.g. col. 10, lines 26-28; col. 30, lines 30-47). In one type of device, the device (refers to instant claim 20) comprises a first substrate with a first organic layer that comprises a recognition moiety, which interact with the analyte, a second substrate, and a mesogenic layer between the first and second substrate (see e.g. col. 5, lines 44-59; col. 20, lines 4-52; col. 40, line 36 thru col. 41, line 66). In another type of device, the optical cell (refers to instant claims 17 and 19) comprises two supports, an anisotropic gold films, two self-assembled monolayers, a spacer that separate the two self-assembled monolayers, and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claim 18)(see e.g. col. 40, lines 36 thru col. 41, line 41; fig. 2). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. col. 42, lines 34-38). The two self-assembled monolayers comprises a self-assembled monolayer form from biotin-(CH₂)₂[(CH₂)₂O]₂NHCO(CH₂)₁₁SH(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent) and a self-assembled monolayer form from CH₃(CH₂)₇SH(C₈SH) (refers to instant claimed second surface)(see e.g. col. 40, line 56 thru col. 41, line 19). The support is a glass slide (see e.g. fig. 2).

Additionally, the claimed invention further differs from the prior art teachings only by the recitation of the following process limitations: a) "*The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface*"; b) for claim 3, "*the biomolecule*

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recognition agent is deposited on the same side of the support as the biochemical blocking layer before the biochemical blocking layer is rubbed"; and for claim 10 "at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the at least two regions of the rubbed surface have different sensitivities towards the target species".

These limitations do not differentiate the claimed apparatus from the apparatus of Abbott et al.

since the apparatus of Abbott et al. meets all the structural limitation of the claimed apparatus.

See MPEP § 2114, which states:

MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM FROM THE PRIOR ART

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (The preamble of claim 1 recited that the apparatus was "for mixing flowing developer material" and the body of the claim recited "means for mixing ..., said mixing means being stationary and completely submerged in the developer material". The claim was rejected over a reference which taught all the structural limitations of the claim for the intended use of mixing flowing developer. However, the mixer was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.).

Here, the apparatus of Abbott et al. comprises a support, an organic layer attached to the support (refers to instant claimed biochemical blocking layer), and a recognition moiety attached to the organic layer (refers to instant claimed biomolecule recognition agent), and thus meets all the structural limitation of the claimed apparatus.

Anawis et al. disclose a device for detecting the presence of an analyte (antibody) in a test sample. The assay device includes a solid phase and the ligand (antigen) is immobilized upon the solid phase (see e.g. col. 2, lines 52-55). In order to prevent non-specific binding of protein to the solid phase when the reaction mixture containing a specific binding member is contacted to the solid phase by using a blocking agent such as bovine or equine serum albumin.

The combine teachings of Abbott et al. and Anawis et al. are obvious over the presently claimed invention as discussed in paragraph 14 above. However, the combination of device of Abbott et al. and Anawis et al. differs from the presently claimed invention by failing to disclose support that includes material such as silica and a crosslinking agent that immobilizes the biochemical blocking compound onto the support wherein the crosslinking agent is glutaraldehyde.

Weetall teaches a method of immobilizing protein on an inorganic support by way of a bifunctional "linker" substance (see e.g. pg. 166, lines 13-19). One type of bifunctional linker is glutaraldehyde (see e.g. pg. 167, lines 1-12; pg. 167, fig. 6). The inorganic support includes material such as glasses, silicas or metal oxides (see pg. 158, line 38 thru pg. 159, line 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose support that includes material such as silica and a crosslinking agent that immobilizes the biochemical blocking compound onto the support wherein the crosslinking agent is glutaraldehyde as taught by Weetall in the apparatus of Abbott et al. and Anawis et al. One of ordinary skill in the art would have been motivated to disclose support that includes material such as silica and a crosslinking agent that immobilizes the biochemical blocking compound onto the support wherein the crosslinking agent is glutaraldehyde in the apparatus of Abbott et al. and Anawis et al. for the type of support use and the type of crosslinking agent use would be a choice of experimental design and is considered within the purview of the cited prior art. Additionally, both Abbott et al. and Weetall disclose that there is a variety of reaction type that is available for the functionalization of the substrate surface and thus the type use depend on the specific needs of the application (Abbott: col. 21, lines 17-26;

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Weetall: pg. 182, lines 27-32). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Abbott et al., Anawis et al., and Weetall because Weetall shown the success of derivatizing the inorganic substrate with the glutaraldehyde (pg. 167, fig. 6).

Therefore, the combine teachings of Abbott et al., Anawis et al., and Weetall do render the apparatus of the instant claims *prima facie* obvious.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810.

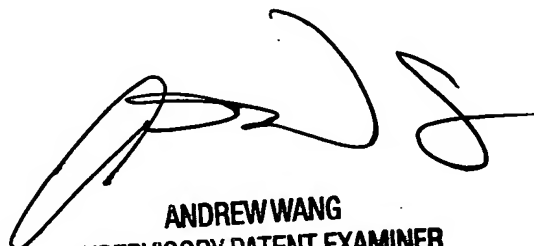
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The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
April 16, 2006



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